



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,723	12/15/2005	Richard Einstein	BJS-3665-166	5102
23117 7590 03/23/2010 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER				
AEDER, SEANE				
ART UNIT		PAPER NUMBER		
1642				
MAIL DATE		DELIVERY MODE		
03/23/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/560,723

Applicant(s)

EINSTEIN ET AL.

Examiner

SEAN E. AEDER

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 16 and 35-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 16, 37, 39, 42 is/are allowed.
- 6) ☒ Claim(s) 2, 35, 36, 38, 40, 41 and 43-47 is/are rejected.
- 7) ☒ Claim(s) 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Detailed Action

The Amendments and Remarks filed 2/19/10 in response to the Office Action of 8/21/09 are acknowledged and have been entered.

Claims 35-47 have been added by Applicant.

Claims 1, 2, 16, and 35-47 are pending.

Claims 2 and 16 have been amended by Applicant.

Claims 1, 2, 16, and 35-47 are currently under examination.

The following Office Action contains NEW GROUNDS of rejections necessitated by amendments.

Rejections Withdrawn

The rejection of claim 16 are rejected under 35 U.S.C. 102(b) is withdrawn.

The rejection of claim 16 are rejected under 35 U.S.C. 102(e) is withdrawn.

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2 remains rejected and claims 35, 36, 38, 40, 41, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Schlegel et al (WO 01/60860 A2; 8/23/01) for the reasons stated in the Office Action of 8/21/09 and for the reasons set forth below.

Schlegel et al teaches a 518 base pair nucleic acid prostate expression marker sequence which encodes the entire amino acid sequence of instant SEQ ID NO:183 (see sequence comparison below and see sequence spanning pages 9917-9918 of WO 01/016860 publication at http://www.wipo.int/pctdb/en/wads.jsp?IA=US2001005171&LANGUAGE=EN&ID=09006361800343a8&VOL=26&DOC=000001&WO=01/060860&WEEK=34/2001&TYPE=A2&DOC_TYPE=PAMPH&PAGE=1. Note the numbering on the pages themselves starts with page 1 as being the first page of the tables in the application not the first page of the application (i.e. page 9806 of the tables is page 9917 of the application), in particular). Schlegel et al further teaches a kit comprising said 518 base pair nucleic acid sequence bound to a detectable label, including a radiolabel, a fluorescent compound, or an enzyme (see page 32, in particular).

Alignment Scores:

Pred. No.:	6.12e-07	Length:	518
Score:	90.00	Matches:	18
Percent Similarity:	100.0%	Conservative:	0
Best Local Similarity:	100.0%	Mismatches:	0
Query Match:	100.0%	Indels:	0
DB:	5	Gaps:	0

US-10-560-723-183 (1-18) x ABV51009 (1-518)

```
Qy          1 ValGluThrGluPheHisArgValSerGlnAspGlyLeuAspLeuLeuThrSer 18
              |
Db          396 GTAGAGACGGAGTTTCATCGTGTTAGCCAGGATGGTCTCGATCTCCTGACCTCG 449
```

In the Reply of 2/19/10, Applicant argues that Schlegel et al does not teach the specific sequence, probe, or component of the claims. Applicant further states that the cited art may describe larger nucleic acid sequences containing a sequence encoding SEQ ID NO:183 of the present application but the cited art is not believed to describe or suggest the presently claimed invention. Applicant further requested a copy of WO 01/60860 A2.

The amendments to the claims and the arguments found in the Reply of 2/19/10 have been carefully considered, but are not deemed persuasive. In regards to the argument that that Schlegel et al does not teach the specific sequence, probe, or component of the claims, Schlegel et al teaches sequences, probes, and components of the claims (see above).

In regards to the statement that the cited art is not believed to describe or suggest the presently claimed invention, the cited art teaches products encompassed by the claims (see above). Further, the instant claims encompass the large "nucleic acid sequences containing a sequence encoding SEQ ID NO:183 of the present application" taught by Schlegel et al.

In regards to Applicant's requires to provide a copy of WO 01/60860 A2, the Office Action of 8/21/09 was mailed with a copy of WO 01/60860 A2. Further, a

Claim 2 remains rejected and claims 35, 36, 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Venter et al (US 6,812,339 B1; 11/2/04).

Pred. No.:	5.7e-07	Length:	601
Score:	90.00	Matches:	18
Percent Similarity:	100.0%	Conservative:	0
Best Local Similarity:	100.0%	Mismatches:	0
Query Match:	100.0%	Indels:	0
DB:	3	Gaps:	0

Qy 1 ValGluThrGluPheHisArgValSerGlnAspGlyLeuAspLeuLeuThrSer 18
 |||||
Db 488 GTAGAGACGGAGTTTCACCGTGTTAGCCAGGATGGTCTTGATCTCCTGACCTCG 541

In the Reply of 2/19/10, Applicant argues that Venter et al does not teach the specific sequence, probe, or component of the claims. Applicant further states that the cited art may describe larger nucleic acid sequences containing a sequence encoding SEQ ID NO:183 of the present application but the cited art is not believed to describe or suggest the presently claimed invention.

The amendments to the claims and the arguments found in the Reply of 2/19/10 have been carefully considered, but are not deemed persuasive. In regards to the argument that that Venter et al does not teach the specific sequence, probe, or component of the claims, Venter et al teaches sequences, probes, and components of the claims (see above).

In regards to the statement that the cited art is not believed to describe or suggest the presently claimed invention, the cited art teaches products encompassed by the claims (see above). Further, the instant claims encompass the large "nucleic acid sequences containing a sequence encoding SEQ ID NO:183 of the present application" taught by Venter et al.

New Objections

Claim 40 is objected to because of an apparent typographical error. Claim 40 recites "being bond to". It is noted the following amendment would obviate this rejection: "being ~~bond~~ bound to". Proper correction is required.

New Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 44-47 are rejected under 35 U.S.C. 101 because claims 44-47, as written, do not sufficiently distinguish over polynucleotides as they exist naturally because the

claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Allowable Subject Matter

Claims 1, 16, 37, 39, and 42 are allowed.

Summary

Claims 2, 35, 36, 38, 40, 41, and 43-47 are not allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642

Application/Control Number: 10/560,723
Art Unit: 1642

Page 9